REMARKS

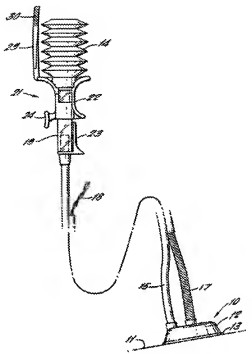
Claims 7, 10-12, 28-35, 37-40, 43, 46 and 54-59 are pending in the application with entry of this Amendment. Claims 7, 28 and 43 are currently amended. The claim amendments do not present new matter. It is respectfully requested that these claims be reinstated upon allowance of respective independent claims from which they depend. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Claims 7, 10, 11, 28, 30, 40, 43, 46, 47 and 54-59 Are Patentable Over Samson, Geeham, Lundback and Ostroff

Independent claims 7, 28 and 43 and respective dependent claims 10, 11, 30, 40, 46, 47 and 54-59 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,185,442 to Samson ("Samson") in view of U.S. Patent no. 5,295,481 to Geeham ("Geeham"), U.S. Patent No. 4,736,749 to Lundback ("Lundback") and U.S. Patent No. 7,149,575 to Ostroff *et al.* ("Ostroff"). Applicant respectfully traverses the rejection in view of the collective deficiencies of the cited references and the inaccurate characterization of cited references in the Office Action.

It is alleged in the Office Action, p. 10, that as described by Samson, "as 17 emerges from 15, the flexible tube has two distal ends, one located adjacent the outer perimeter of the suction cup and one (distal end if 17) located at the center of the suction cup." Fig. 3 of Samson is reproduced below for reference.

FIG. 3.



First, there are various deficiencies with this inaccurate characterization of Samson. As discussed in detail in the prior amendment, Samson actually discloses that "15" is a "tube" that interconnects a vacuum source or bellows 14 and the suction cup 10 (Samson, col. 3, lines 44-46), and that "17" is actually a coiled wire (Samson, col. 3, line 49). More specifically, Samson refers to "a second electrode formed of coiled wire 17" and explains that the first electrode is electrode 16 that is centrally disposed within the body of the suction cup 15, and that both of the first and second electrodes are connected by wiring 18 to a diagnostic monitoring apparatus 19. As illustrated in various figures of Samson, the wire 17 runs along an outer surface of the tube 15. Samson, Fig. 3, clearly illustrates this structure both at the distal end of the wire 17 and at the proximal end where wiring 18 extends from 17, not 15.

Accordingly, contrary to what is alleged in the Office Action, the wire 17 of the second electrode does not "emerge" from the suction tube. This Office Action allegation is clearly contrary to what is disclosed and illustrated by Samson. Given this very different structure, it is noteworthy that the Office Action, p. 10, has not cited any section of Samson, text or figure, which actually discloses wire 17 emerging from the suction tube 15. Accordingly, the Office Action allegations contradict the undisputable structure described and illustrated by Samson.

Second, as is well understood, the second electrode wire 17 is not, and is not designed to be or capable of, applying suction. Accordingly, in addition to the mischaracterization of Samson as noted above, the cited reference clearly fails to disclose "a flexible tube defining a central axis and having a proximal end and a distal end through which suction is applied."

Third, given the particular structure disclosed by Samson, Samson fails to disclose "a flexible suction device, the suction device being connected to and coaxial with the distal end of the tube" as recited in claims 7, 28 and 43. The only component that is arguably "coaxial with" the suction device is the wire 17, and as discussed above, the wire 17 cannot support the rejection since the wire, as is well understood and as its name implies, is used to conduct electrical current and is not for applying suction. The tube 15, as shown in Samson, Fig. 3 above, does not define a central axis and a suction device that is connected to and coaxial with the distal end of tube and instead is near the top left edge of the wall such that the suction cup 10 is <u>not coaxial</u> with the tube 15. Any allegation to the contrary simply disregards the well understood meaning of coaxial and the undisputable fact that "15" is a suction tube and "17" is not since it is instead a second electrode or wire, consistent with the fact that Samson further explains that the coiled wire 17 is "provided outside the suction cup [10] for making contact with the vaginal wall." Samson (col. 3, lines 49-50).

Fourth, Samson describes a device directed to applying a suction cup 10 to a head 11 of a fetus, in contrast to a suction device that is coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue by suction applied through the flexible tube. The Office Action has failed to address this fact.

Fifth, as conceded in the Office Action, p. 3, Samson further fails to disclose a peripheral sealing surface of the suction device is flexible and the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device such that the tissue stimulation element is not located within an inner space defined by the suction device, wherein the tissue stimulation element is a discrete tissue stimulation element that does not extend around the peripheral sealing surface" and "the tissue electrode is a tissue stimulation element/electrode and a source of stimulation energy operably connected to the stimulation electrode/electrode.

Geeham is cited for the limited purpose of allegedly disclosing a suction device having a peripheral sealing surface with a tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device such that the tissue stimulation element is not located within an inner space defined by the suction device, wherein the tissue stimulation element is a discrete tissue stimulation element that does not extend around the peripheral sealing surface. Geehman, however, does not cure the substantial deficiencies of Samson and has its own deficiencies.

Geeham describes a CPR assist device that includes a column member 16, handles 18a and 18b, and a suction cup member 20. As is well understood, a CPR device is not designed or configured for use as a suction device applied to myocardial tissue, and the Office Action has provided no extrinsic evidence to this effect. Consistent with this conclusion is that Geeham describes a device having defibrillation electrodes 32 (as opposed to a stimulation element that is too small to form a transmural lesion in myocardial tissue) located at the peripheral rim 30 of the suction cup member 20. During use, an aid giver grabs the handles 18a, 18b and administers cycles of compression and expansion by pressing down on the chest and pulling up away from the chest. The suction cup member 10 provides a transfer or force safely and noninjuriously to the patient, and the act of pulling the CPR assist device away from the patient's chest results in a suction action that draws the chest upwardly with the movement of the suction cup member. Geeham (col. 4, lines 19-37). Thus, the device described by Geeham is sufficiently large to be forcefully manipulated by a person grabbing handles 18a, 18b.

Thus, Geeham fails to disclose, and is not related to, the combination of a flexible tube defining a central axis and having a proximal end and a distal end and through which suction is applied, and a flexible suction device, the suction device being connected to and coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue by suction applied through the flexible tube as recited in claims 7 and 28 and a flexible tube defining a central axis and having a proximal end and a distal end and through which suction is applied, and a flexible suction device, the suction device being connected to and coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue by suction applied through the flexible tube as recited in claim 43. In fact, Geeham does not even

mention applying suction through any tube and instead relies only on the deformation of the suction cup 20 to apply suction to the chest.

Geeham also fails to disclose a metallic or metal-based tissue stimulation element configured to emit stimulation energy and that is too small to form a transmural lesion in myocardial tissue and that is used to stimulate tissue and sense electrical activity in the tissue as recited in claims 7 and 28 and metallic or metal based tissue stimulation means for stimulating tissue and sensing electrical activity in the tissue as recited in claim 43. Rather, as conceded in pages 4-5 of the Office Action, Geeham is instead directed to a defibrillation system that utilizes high voltage circuits to provide periodic pretimed shocks of electricity to the electrodes in order to resuscitate a patient. Geeham (col. 3, lines 28, 41, 53-55). Clearly, and as is well understood by persons skilled in the art, defibrillation systems are not related to and do not involve stimulation elements that emit stimulation energy for sensing activity in tissue, e.g., for pacing, recording and determining whether a transmural lesion has been formed. Further, the Office Action has not addressed the fact that the amount of current applied to a person's chest for purposes of defibrillation is much greater than current applied by a stimulation element as recited in Applicant's claims.

Thus, while Geeham may disclose a heart-related device, the structure and functionality of a CPR assist and defibrillation device described by Geeham are very different and not related to Applicant's claims, particularly considering that the CPR assist device does not include a suction device connected to and coaxial with the distal end of the tube and having a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue by suction applied through the flexible tube. Thus, not only is Geeham deficient relative to these claim limitations, but Geeham also teaches away from devices having a shape and size or being removably securable to myocardial tissue by suction applied through the flexible tube given the particular structure and manner in which the device of Geeham is utilized.

Lundback is cited for the very limited purpose of allegedly disclosing a surgical apparatus comprising a flexible tube (8) and a tissue electrode, a cup-shaped suction device (1-3 collectively) and a tissue electrode 30 (tissue contacting side of 30) on the suction device distal surface. Office Action (p. 4). Lundback, however, does not cure the substantial deficiencies of Samson and Geeham and has its own deficiencies.

Claims 7, 28 and 43 recite *inter alia* "a flexible tube defining a central axis and having a proximal end and a distal end through which suction is applied" and "a flexible suction device."

The Office Action, p. 4, relies upon "flexible bending portions of 2" to support the rejection. Lundback describes the following components: a diagnostic or therapeutic arrangement 1, an intermediate element 2, and a backpiece 3. Lundback further explains that the intermediate element 2 is made from silicon rubber or a similar material and has a "relatively rigid ring portion 9." Lundback (col. 3, lines 30-31, 45-46 and 63)

Thus, while Lundback may refer to the intermediate element 2 being made from silicone rubber, Lundback nevertheless explains that the same intermediate element 2 has a "relatively rigid ring portion 9." Lundback (col. 3, line 46; col. 4, line 3) (emphasis added). The Examiner has not explained and has cited no extrinsic evidence establishing that an intermediate component 2 having a relatively rigid ring portion 9 is a flexible suction device.

In addition to the deficiencies of the intermediate element individually, the assembled collection of components 1-3 of Lundback also fail to disclose or form a flexible suction cup. For example, Lundback explains that the cited back piece 3 is **rigid** and that the device 1 is "**rigidly connected**" to the backpiece 3. Lundback, '749 Patent (Abstract; col. 2, line 4; col. 3, line 46) (emphasis added). Moreover, Lundback explains that various components are **press-stud connected** together such that the therapeutic arrangement 1 is "**rigidly connected**" to the rigid backpiece 3. Lundback, '749 patent (col. 3, lines 29-36) (emphasis added).

Accordingly, in addition to explaining that the cited intermediate element 2 has a relatively rigid ring portion 9, Lundback also discloses a device having rigid connections and press-stud connections. Notably, the Office Action failed to establish that the collection of components 1-3 is a "flexible suction device" as recited in Applicant's claims, which is understandable since even the cited component 2 has a "relatively rigid ring portion" and other components are rigid or rigidly connected. Accordingly, the Office Action allegations that rely on one component of a collection of components that form a rigid structure or that have rigidly connected parts cannot support the rejection.

Further, as discussed in the prior Amendment, Lundback also fails to disclose a metallic or metal-based tissue stimulation element configured to emit stimulation energy and that is too small to form a transmural lesion in myocardial tissue, the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device as recited

in claims 7 and 28 and metallic or metal based tissue stimulation means, carried by the peripheral sealing surface of the distal portion of the suction device distal surface as recited in claim 43. Lundback describes an intermediate element 2 having a sealing ring 9, but as shown in Fig. 1 of Lundback, '749 patent, the cited operative part 30 is disposed in a middle portion of the device rather than being carried by a peripheral sealing surface of a suction device.

Lundback also fails to disclose a metallic or metal-based tissue stimulation element configured to emit stimulation energy and configured "such that the tissue stimulation element is not located within an inner space defined by the suction device" as recited in claims 7 and 28 and "such that the tissue stimulation means is not located within an inner space defined by the suction device" as recited in claim 43. Rather, as shown in Fig. 1 of Lundback, '749 patent, the operative part 30 is within the inner space defined by the outer edge of the intermediate element 2. Thus, Lundback describes a configuration that is the opposite of the configuration recited in the claims.

Given these collective substantial deficiencies, no proper combination of the cited references discloses each element of each of independent claims 7, 28 and 43. Ostroff is cited for the very limited purpose of allegedly disclosing electrodes with sensing and pacing capabilities, but Ostroff does not cure these substantial deficiencies. Accordingly, the rejection cannot stand on this basis alone since the four references do not disclose each limitation of each independent claim.

Further, it would not be obvious to modify Samson as taught by Geeham, to provide electrodes on a peripheral distal surface of a suction cup. Samson describes a particular structure in which vacuum is applied to "draw down the electrode 16 into contact with the scalp of the fetus as the cup becomes secured on the fetal head" as opposed to an electrode on a periphery of a suction cup. Thus, the Office Action allegation contradicts the structure and manner in which the centrally disposed electrode is drawn down to contact a fetal head as described by Lundback.

Moreover, it would not be obvious to modify Samson based on the disclosure of Geeham since such a general allegations in the Office Action fail to address the fact that the claims are directed to a device that is attachable to myocardial tissue by suction and emitting stimulation energy to cardiac tissue, whereas Samson is directed to a non-invasive sensing device that is applied to the head of a fetus, and Geeham is related to an unrelated purpose of assisting with CPR by use of a device applied to a chest of a patient. Not only are these devices structured in

different ways, have different sizes, and are used for different purposes, the electrodes described by Geeham apply energy of such a high magnitude to be used for defibrillation, in stark contrast to substantially lower energy levels used with the device of Samson.

Additionally, given the well known manner in which the CPR assist device is intended and designed to be utilized, the device described by Geeham is not designed for securing the suction cup member 20 to myocardial tissue. Instead, as is well known to a person skilled in the art, the assist device described by Geeham is configured for use on an outer surface of a patient's chest, not on the surface of the patient's heart. Geeham (Fig. 1) (illustrating application of device to outer chest surface). In this regard, Geeham describes a system that is used for a very different purpose and in very different ways.

The Office Action has not established, understandably so, that such a device would be utilized by opening a chest cavity and then applying the suction cup member 20 to myocardial tissue. Moreover, it is reasonable to assume that actually applying the suction cup device 20 to myocardial tissue and utilizing the CPR assist device as described by Geeham (by an aid giver pushing down and expanding upon the heart) may result in severe injury and/or death, not only from the compressions, but also from opening the patient's chest.

Additionally, it would not be obvious to modify Samson with the cited structure of Lundback since Lundback, Fig. 4 illustrates a device having a suction tube with an axis that is orthogonal to an axis defined by other components. Thus, Lundback describes a configuration that is the opposite of the configuration recited in the claims and opposite of the configuration described by Samson.

Further, Samson teaches away from "a metallic or metal-based tissue stimulation element … supported on the peripheral sealing surface of the distal portion of the suction device such that the tissue stimulation element is not located within an inner space defined by the suction device" as recited in claims 1 and 28 and "metallic or metal based tissue stimulation means, carried by the peripheral sealing surface of the distal portion of the suction device distal surface such that the tissue stimulation means is not located within an inner space defined by the suction device…" as recited in claim 43 since Samson describes a device in which an electrode 16 is mounted "within the suction cup [10]." Samson (col. 3, lines 47-48 (emphasis added). Samson further explains that this structure allows the electrode 16 to be drawn down into contact with the scalp of the fetus as the cup becomes secured on the fetal head. Samson (col. 3, lines 59-61).

Samson also teaches away from a flexible tube defining a central axis and having a proximal end and a distal end and a flexible suction device, the suction device being connected to and "coaxial with" the distal end of the tube as recited in Applicant's claims. Rather, as discussed above, Samson is directed to a central electrode 16 within the space defined by a suction cup 10 that is drawn into contact with a fetus scalp by suction, and the wire 17 is centrally disposed for connection to this central electrode 16.

Geeham also teaches away from a suction device that is "removably securable to myocardial tissue by suction applied through the flexible tube" since Geeham relates to CPR devices, and it is well understood that such CPR devices do not involve opening a patient's chest to apply a suction cup to a myocardial surface of the patient since doing so may result in server injury and/or death of the patient.

Further, to the extent that the suction level achieved utilizing a suction cup 20 is sufficient or advisable for performing CPR, Geeham also teaches away from an external source of suction since such additional suction may result in excessive pulling on the patient's chest.

Lundback also teaches away from a flexible tube defining a central axis and having a proximal end and a distal end and a flexible suction device since as discussed above, Lundback actually refers to rigid and stiff materials and rigid connections achieved using press-stud connections.

Lundback also teaches away from such a flexible tube being coaxial with a suction device since Lundback describes a configuration that is the opposite of the configuration recited in Applicant's claims.

In view of the very different structures, functions and capabilities of the cited components of the four cited references, Applicant respectfully submits that the alleged combination of piecemeal components of these very different structures and methods described thereby do not involve combining or substituting elements according to known methods to achieve predictable results or designs (particularly in view of the substantial and determinative deficiencies of Samson), and that in view of these substantial differences, it would not be obvious to try to the alleged combinations. Further, various references teach away from aspects of claims independent claims 7, 28 and 43. Accordingly it is respectfully submitted that these claims are patentable over the four cited references.

Dependent claims 10, 11, 30, 40, 46, 47 and 54-59 incorporate the elements and limitations of respective independent claims 7, 28 and 43 and, therefore, are also believed patentable over these references.

Accordingly, Applicants respectfully request that the rejection of claims 7, 10, 11, 28, 30, 40, 43, 46, 47 and 54-49 under 35 U.S.C. §103(a) be withdrawn.

II. Claims 34 and 35 Are Patentable Over Samson, Geeham Lundback and Colliou

Claims 34 and 35 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Samson in view of Geeham and Lundback and further in view of Colliou. Colliou is cited for the very limited purpose of allegedly disclosing certain stimulation pulses, but Colliou does not cure the substantial and determinative deficiencies discussed above.

Accordingly, it is respectfully requested that the rejection of these claims under §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment and allowance of the application in view of the forgoing remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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Dated: June 7, 2010

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